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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,803	01/23/2007	Patrick Soon-Shiong	252887	4888
23460 7590 11/21/2007 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER AULAKH, CHARANJIT	
			ART UNIT 1625	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/583,803

Applicant(s)

SOON-SHIONG ET AL.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 55-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/8/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

1. According to a preliminary amendment filed on June 22, 2006, the applicants have canceled claims 1-54 and furthermore, have added new claims 55-108.
2. Claims 55-108 are now pending in the application.

### ***Specification***

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 99-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, *In re*, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least

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four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

The instant specification shows inhibitory effect of some exemplified compounds in vitro using MX-1 9 human breast carcinoma ) cells ( see example 17 and table 1 on pages 26-27 ). Based on these teachings, the instant compounds will have utility for treating breast cancer. However, there is no teaching or guidance present in the specification how the instant compounds will have utility in treating every type of known cancer in the art. There are no working examples present showing inhibitory effect of instant compounds in any other cell line besides breast carcinoma. There is no teaching either in the prior art or the instant specification that all camptothecin compounds ( whether unsubstituted or substituted with R1-R4 groups ) are well known to have therapeutic utility in treating every known cancer in the art. The instant compounds of formula of claim 55 encompasses hundreds of thousands of compounds based on the values of variables R, R1, R2, R3 and R4 and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in every known cancer cell line in vitro and hence their utility for treating every known cancer.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 55-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 55-108, the term --- derivatives --- is vague and indefinite since its meaning is not clear. This term is not defined in the specification. The applicants are suggested to delete this term.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 55-58, 60, 77, 78 and 97-108 are rejected under 35 U.S.C. 102(a) as being anticipated by Du ( Bioorg. & Medicin. Chem., cited on applicant's form 1449 ).

Du discloses Semisynthesis of DB-67 and other silatecans from camptothecin. The compounds 6-9 ( see figure 2 on page 454 ) disclosed by Du anticipate the instant claims when R represents alkyl group ( methyl ) in the instant compounds.

9. Claims 55, 57, 63, 97 and 99-108 are rejected under 35 U.S.C. 102(a) as being anticipated by Pan ( Bioorg. & Medicin. Chem. Lett., cited on applicant's form 1449 ).

Pan discloses Regioselective synthesis and cytotoxicities of camptothecin derivatives. The compounds 6a and 6b ( see scheme 1 on page 3740 as well as table 1 on page 3741 ) disclosed by Pan anticipate the instant claims when R represents (CH<sub>2</sub>)<sub>n</sub>OR<sub>5</sub> in the instant compounds.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 55-58, 60, 77, 78 and 97-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Wani ( J. Org. Chem. ).

Wani discloses new alkaloids from camptotheca acuminata having antitumor activity.

The compound 5 ( see chart I on page 1364 ) disclosed by Wani anticipate the instant claims when R represents alkyl group ( methyl ) in the instant compounds.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 59, 61, 62, 64-76 and 79-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Du ( Bioorg. & Medicin. Chem. , cited on applicant's form 1449 ) in view of Cao ( U.S. patent 5,968,943 and 6,407,239, cited on applicant's form 1449 ) or Wall ( U.S. Patent 6,040,313, cited on applicant's form 1449 ).

Du discloses Semisynthesis of DB-67 and other silatecans from camptothecin. The diester compounds 6-8 ( see figure 2 on page 454 ) disclosed by Du meets all the limitations of instant claims ( have C(O)O- groups at 10<sup>th</sup> and 20<sup>th</sup> position of camptothecin ) except that instant R or R4 groups are different in the instant claims.

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However, Cao ( U.S. patent 5,968 and 6,407,239 ) as well as Wall ( U.S. patent 6, 040, 313 ) discloses mono esters of camptothecin having ester group at 20<sup>th</sup> position of camptothecin ( see claim 1 of each these patents) having value of instant variable R as C2-C15 alkyl group, alkenyl group, an aryl group and (CH<sub>2</sub>)<sub>m</sub>NR<sub>10</sub>R<sub>11</sub> groups and furthermore, have various values of instant variable R<sub>4</sub> including alkyl group etc.


Therefore, it would have been obvious to one skilled in the art to prepare instant diesters by modifying R group of diesters of Du with R groups disclosed in the monoesters of the three cited U.S. patents since R group as well as R<sub>4</sub> group is not critical for preparing diesters (esterification at 10<sup>th</sup> and 20<sup>th</sup> position of camptothecin ).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
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